



## **Economic Impact Analysis Virginia Department of Planning and Budget**

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### **18 VAC 110-20 – Regulations Governing the Practice of Pharmacy and 18 VAC 110-50 – Regulations Governing the Wholesale Distributors, Manufacturers and Warehouses**

**Department of Health Professions**

August 1, 2005

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The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with Section 2.2-4007.H of the Administrative Process Act and Executive Order Number 21 (02). Section 2.2-4007.H requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. The analysis presented below represents DPB's best estimate of these economic impacts.

### **Summary of the Proposed Regulation**

Currently, regulations for wholesale distributors, manufacturers and warehouses of pharmaceuticals are within Chapter 18 VAC 110-20 – Regulations Governing the Practice of Pharmacy. The Board of Pharmacy (board) proposes to create a new chapter, 18 VAC 110-50, for the regulation of wholesale distributors, manufacturers and warehouses. In doing so, the board proposes to delete language on wholesale distributors, manufacturers and warehouses of pharmaceuticals from Chapter 18 VAC 110-20. Additionally, the board proposes numerous amendments, including to: 1) no longer permit wholesale distributors, manufacturers or warehouses to operate from a private dwelling, 2) create a limited-use wholesale distributor license for entities who only distribute medical gases or over-the-counter drugs, 3) require new detailed information from non-resident wholesale distributors, 4) require criminal background checks for wholesale distributors' responsible party, and 5) establish due diligence requirements

for wholesale distributors purchasing prescription drugs from another wholesale distributor not residing in and licensed in Virginia.

## **Estimated Economic Impact**

The board proposes several amendments designed “to increase its oversight of the wholesale distribution market in order to prevent opportunities for counterfeiting of drugs and ensure the integrity, safety and efficacy of drugs or devices distributed in the Commonwealth.” According to the Department of Health Professions (department):

Over the past several years the incidences of counterfeit prescription drug products detected in the U.S. legitimate drug supply system has been increasing. In the 1990's, the average number of counterfeit drugs found in the supply system was approximately 5 per year. According to FDA, this number has jumped to over 20 a year since 2001.

Of the drugs which have (been) found to be counterfeited, many are expensive injectable drugs used to treat our sickest population, patients undergoing cancer chemotherapy, AIDS patients, and patients with kidney disease undergoing renal dialysis. Under-treatment or non-treatment in these patients due to receiving counterfeit drug products would lead to exacerbation of the disease state or other symptoms, and possibly death. In at least one case, a counterfeit product purporting to be Procrit, was not only found to contain little to no active drug, but was also contaminated with acinetobacter and pseudomonas bacteria, which could easily lead to a deadly infection in a normal patient, and is much more dangerous to a patient who already has a compromised immune system.

Counterfeiting has become very sophisticated in that often the counterfeit products look almost identical to the real product. Much of the counterfeiting takes place in garage labs where there is no consideration of maintaining even sanitary conditions much less sterile conditions. The counterfeiting business is very lucrative. There is little overhead, and with the high cost of some prescription drugs, very profitable. In one Florida case, one company selling counterfeit drugs to a Tennessee wholesaler received \$17 million in wire

transfers. It has become more than dealing in illegal street drugs and less risky in terms of penalties if caught.

Since the costs of counterfeit drugs to patients' health can be quite serious, and the risk of counterfeit drugs being distributed in Virginia seems more than negligible, proposed regulations that could effectively deter the distribution of counterfeit drugs in Virginia would be significantly beneficial.

Under the current regulations, wholesale distributors, manufacturers and warehouseers are allowed to operate from a private dwelling if there is a separate business entrance and it is open for inspection at all time during normal business hours. The board is now proposing to prohibit the basing of these of types businesses out of homes due to news of illegal activities in other states. For example, in Florida there have been several instances of counterfeit prescription drug businesses that operated from a garage and did not maintain a legitimate business address.<sup>1</sup> According to the department, now that Florida increased its oversight of the wholesale distributor business and began serious enforcement efforts, these businesses are looking for other states with less strict laws and regulations. Under the proposed regulations if a licensee's business is limited to medical gases or over-the-counter drugs, an applicant could apply for a limited-use license that would allow operation from a residence.

It is conceivable that a legitimate wholesale distributor, for example, may wish to operate out of a large private dwelling. The cost of switching operations to a different location to avoid violating the proposed prohibition from home operation would be substantial. However, the department is not aware of any wholesale distributors, manufacturers or warehouseers having ever operated out of a dwelling in Virginia. To the extent that this proposed prohibition is enforced, it will raise costs for those businesses that would have otherwise operated out of a dwelling (except for businesses limited to medical gases or over-the-counter drugs). Based upon available information, only counterfeiters<sup>2</sup> have operated out of private dwellings. Thus, this proposal would likely raise costs primarily for counterfeiters, potentially discouraging their operation in Virginia. Thus, this proposal has the potential to provide a net benefit for the Commonwealth.

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<sup>1</sup> Source: Department of Health Professions

<sup>2</sup> Other than the exempted businesses limited to medical gases or over-the-counter drugs.

The proposal also produces a potential cost for Virginia. If at some point in the future a legitimate non-exempted business found that it would be cost effective to operate out of a residence, this would be prohibited under the proposed language. If the board believed it could effectively keep out counterfeiters without simultaneously limiting legitimate businesses, that would be preferred. Nevertheless, to the extent that it does discourage the manufacture and distribution of counterfeit drugs in Virginia, the proposed prohibition of the operation of wholesale distributors, manufacturers and warehouseers from a private dwelling, other than businesses limited to medical gases or over-the-counter drugs, will likely provide a net benefit for the Commonwealth.

As mentioned above, the board proposes to create a limited-use wholesale distributor license for entities who only distribute medical gases or over-the-counter drugs. In addition to being permitted to operate out of a residence if desired, businesses with such a limited-use wholesale distributor license will save some staff time due to not being required to report the full set of information required for full wholesale distributor licensees. Specifically, the proposed regulations state that “The board ... may waive certain requirements of regulation based on the limited nature of such distribution.” The department has indicated that the certain requirements that may be waived refer to reporting information that is not considered necessary for these limited-use wholesalers to report to maintain safety for the public. Thus, the proposed limited-use wholesale distributor license will provide a net benefit.

The board also proposed to require new detailed information from non-resident wholesale distributors, including the address, square footage, security and alarm system description, temperature and humidity control, and other relevant information of the facility or warehouse space used for prescription drug storage and distribution. The non-resident wholesale distributors should be able to easily collect and report this information in less than a day. The board believes the information will allow the department to be better able to monitor for product integrity and protect the public from counterfeiting. To the extent that the information does improve monitoring and reduces the probability of counterfeiting, the proposed requirements will likely provide a net benefit.

Additionally, the board proposes to require that applications for a new wholesale distributor license or for registration as a non-resident wholesale distributor, or for any change of

ownership, include a criminal history record check for the wholesale distributor's responsible party. According to the department, the criminal background check costs \$15. This is pertinent information for the board to monitor the industry in Virginia. Given the small cost to businesses, it will likely provide a net benefit for the Commonwealth.

The board proposes due diligence requirements for wholesale distributors purchasing prescription drugs from another wholesale distributor not residing in and licensed in Virginia. Specifically,

A. Prior to the initial purchase of prescription drugs from another wholesale distributor not residing and licensed in Virginia, a wholesale distributor shall obtain, and update annually, the following information from the selling wholesale distributor:

1. A copy of the license to wholesale distribute from the resident state;
2. The most recent facility inspection report, if available;
3. A list of other names under which the wholesale distributor is doing business, or was formerly known as;
4. A list of principals, directors, officers, or any shareholder who owns 10% or more of outstanding stock in any non-publicly held corporation;
5. A list of all disciplinary actions by state and federal agencies;
6. A description, including the address, dimensions, and other relevant information, of each facility or warehouse used for drug storage and distribution;
7. A listing of any manufacturers for whom the wholesale distributor is an authorized distributor of record.

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C. Prior to the first purchase of drugs from another wholesale distributor not residing in and licensed in Virginia, the purchasing wholesale distributor shall secure a national criminal background check of all of the wholesale distributor's owners, corporate officers, and the person named as the responsible party with the resident board or licensing agency.

The Healthcare Distribution Management Association has stated that legitimate businesses already do this type of due diligence as a matter of practice.<sup>3</sup> For businesses that already ask for all of this information and secure the criminal background checks, there will be no new cost. Businesses that do not already ask for all of this information or do not conduct the criminal background checks will incur new costs. As stated earlier, the criminal background checks cost \$15 per person. The purchasing business will need to spend a small amount of time requesting the information. If the out-of-state wholesale distributor has sold to legitimate businesses in the past, it should have most or all of the requested information readily available.<sup>4</sup> Thus, based on the Healthcare Distribution Management Association's statement, the proposed due diligence requirements will not produce significant new costs for legitimate businesses. The due diligence requirements essentially require that wholesale distributors who purchase prescription drugs from another wholesale distributor not residing in and licensed in Virginia, be knowledgeable about the backgrounds of the sellers. Given this responsibility, the purchaser may be more careful concerning the source of the products that they will sell in Virginia. This can potentially decrease the likelihood that counterfeit drugs will be sold in the Commonwealth. To the extent that the proposed due diligence requirements do decrease the likelihood that counterfeit prescription drugs are sold in Virginia, the benefits of the proposal will likely exceed the costs.

## **Businesses and Entities Affected**

The proposed regulations affect the 125 wholesale distributors, 558 non-resident wholesale distributors, 92 manufacturers, and 29 warehouse users licensed in Virginia.<sup>5</sup>

## **Localities Particularly Affected**

The proposed regulations affect localities throughout the Commonwealth.

## **Projected Impact on Employment**

The proposed amendments will not likely significantly affect employment levels.

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<sup>3</sup> Source: Department of Health Professions

<sup>4</sup> This statement is based on the statement by the Healthcare Distribution Management Association (via the Department of Health Professions) that legitimate businesses already do this type of due diligence as a matter of practice.

<sup>5</sup> Figures from the Department of Health Professions

## **Effects on the Use and Value of Private Property**

The proposed amendments will not likely have a large impact on the use and value of private property for most wholesale distributors, manufacturers, and warehouseers. Wholesale distributors who only distribute medical gases or over-the-counter drugs save some staff time due to not being required to report the full set of information required for full wholesale distributor licensees. The proposal to require that applications for a new wholesale distributor license or for registration as a non-resident wholesale distributor, or for any change of ownership include a criminal history record check for the wholesale distributor's responsible party will cost these businesses \$15.

Wholesale distributors who purchase prescription drugs from another wholesale distributor not residing in and licensed in Virginia, and who currently do not conduct criminal background checks of the owners, corporate officers, and the person named as the responsible party, will need to conduct these checks, costing \$15 per owner, corporate officer, and responsible party (if not an owner or corporate officer). Out-of-state wholesale distributors who do not currently provide the full set of proposed required due diligence information when selling to Virginia wholesalers will need to spend additional staff time assembling the required information.

## **Small Businesses: Costs and Other Effects**

The department has stated that it is not aware of any wholesale distributors, manufacturers or warehouseers having ever operated out of a dwelling in Virginia. If in the future such a business wished to operate out of a residence, the prohibition on this activity would clearly be costly. The firm would need to obtain access to additional property.

The proposed creation of a limited-use wholesale distributor license for entities who only distribute medical gases or over-the-counter drugs will save these businesses some staff time due to not being required to report the full set of information required for full wholesale distributor licensees.

The proposal to require that applications for a new wholesale distributor license or for registration as a non-resident wholesale distributor, or for any change of ownership include a criminal history record check for the wholesale distributor's responsible party will cost these businesses \$15.

Wholesale distributors who purchase prescription drugs from another wholesale distributor not residing in and licensed in Virginia, and who currently do not conduct criminal background checks of the owners, corporate officers, and the person named as the responsible party, will need to conduct these checks, costing \$15 per owner, corporate officer, and responsible party (if not an owner or corporate officer). Out-of-state wholesale distributors who do not currently provide the full set of proposed required due diligence information when selling to Virginia wholesalers will need to spend additional staff time assembling the required information.

### **Small Businesses: Alternative Method that Minimizes Adverse Impact**

All of the proposed new requirements are designed to decrease the likelihood of the manufacture, distribution and sale of counterfeit drugs in Virginia. It is possible that not all of the proposed requirements are required to effectively prevent this illegal activity. If in the future, for example, it is believed that an applicant who can demonstrate possession of all of the equipment and designations required for legitimate business to be conducted wishes to operate from property that includes living quarters, perhaps the board would allow such business to take place. At this time, though, it is not known whether fewer restrictions would effectively minimize counterfeiting activity in the Commonwealth.